**Remarks and Response**

Applicant appreciates the time and consideration taken by the Examiner in the in-person interview for this case with Applicant and Applicant's representative on October 20, 2006. At the interview, the subjects discussed included, the content of the claims, the nature of the invention, the 101 and 112 rejections, and further defining the methods steps.

To more clearly define the method of the invention in the broadest terms, claim 250 is now added to the application, replacing and supported by now cancelled claim 201. Accordingly all claims 1-249 are now cancelled from the present matter without prejudice to ongoing prosecution of the subject matter of those claims in continuing applications. This further resolves the Examiner's objections regarding the previously missing claim and the improper dependencies. Consequently, Applicant asks that the claim objections be withdrawn as moot.

Nevertheless, new claims 250-296 are fully supported by the now-cancelled claims, in further light of the steps provided in Applicant's flow-charts in the figures, and in the remainder of the specification. Figures 1-3, at least, refer to a user interface or use of a user computer, supporting the computerization referred to in claim 294.

No new matter has been added.

**Response to the Rejection under 35 USC §112, second paragraph**

The Examiner has rejected Applicant's pending claims under 35 USC §112, second paragraph as indefinite because steps of Applicant's claimed method are not fully provided. In making this rejection the Examiner has kindly suggested the subject matter that should be provided in such method steps. However, not all of the Examiner's proposed steps are part of Applicant's presently claimed method, because in some cases steps proposed by the Examiner may have been concluded prior to the beginning of the claimed method. For example, as provided in claim 250, the identity of the new use for, or useful characteristic of the product or device is derived and stored according to the steps comprising accessing an adverse event data source; analyzing and comparing adverse event data associated with a product of manufacture or device, with at least one previously-known adverse event associated with the product or device; and identifying at

least one new essential adverse event associated with the product or device from the adverse event data, and then responsive to that identification, identifying the at least one new characteristic of, or use for, the product or device, and:

documenting inventorship of the at least one new characteristic of, or use for, the product or device; and

creating a proprietary essential adverse event information database, which stores the one new characteristic or use, wherein the database comprises at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication.

These steps distinguish Applicant's **new** use or characteristic of the product or device as unique. No agency, such as the FDA, creates *proprietary* new uses, nor does it create an essential adverse event information database comprising patent information in conjunction with documenting inventorship, even if the subject of the new use or characteristic is a drug interaction. Accordingly, Applicant's method meets the requirements under 35 USC §112, second paragraph.

It is well established that claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their broadest reasonable interpretation. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983). *In re Sneed*, 218, USPQ 385, 388 (Fed. Cir. 1983). The test for definiteness under the 112 standard is whether one skilled in the art would understand the bounds of the claim when read in the light of the specification. "If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, 112 demands no more. The degree of precision necessary for adequate claims is a function of the nature of the subject matter." *Orthokinetics Inc. v. Safety Travel Chairs Inc.*, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986); *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1109, 1194 (Fed. Cir. 1993). *Miles Laboratories Inc. v. Shandon Inc.*, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993).

Thus, the "distinctly claiming" requirement of 112 is met by Applicant's claims, in that the claims have *clear and definite meaning when construed in the light of the complete patent document*. While the claim language under consideration may be broad, breadth is not indefiniteness. Instead, the second paragraph of section 112 simply

requires the claims to set forth and circumscribe a particular area with a reasonable degree of precision and particularity. *Buell v. Beckestrom*, 22 USPQ2d 1128, 1133 (BPAI 1992).

"The public is entitled to know the scope of the claims, but must look to both the patent specification and the prosecution history, especially where there is doubt concerning the scope of the claims." *Texas Instruments v. ITC*, 10 USPQ2d 1257, 1264 (Fed. Cir. 1989). "[I]f the claims, read in the light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." Quoting *Shatterproof Glass Corp. v. Libbey Owens Ford Co.*, 225 USPQ 634, 641 (Fed. Cir. 1985). *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986). Consequently, so long as the method is clear, it is not requisite under patent law that absolutely every step of the claimed method be delineated in the claim, if one of ordinary skill can determine the additional information from the specification or prosecution history. Accordingly, since Applicant's claims are distinct and the information supporting the claims is provided by the specification, that is, in the patent document as a whole, the rejection under 35 USC 112, second paragraph, is moot. Applicant, therefore, respectfully asks that the rejection be withdrawn.

**Response to the Rejection under 35 USC §101**

The Examiner has rejected Applicant's pending claims under 35 USC §101, as directed to non-statutory subject matter. In making this rejection the Examiner has interpreted Applicant's invention as directed to the natural exception of a "natural phenomenon," and as such is not patentable.

In response, Applicant points out that the subject matter of this invention is limited to new uses of man made items, such as a product of manufacture or device. Applicant also argues that it is not a natural phenomenon to document inventorship of the new characteristic of, or use for, the product or device. Nor is it a natural phenomenon to creating a proprietary essential adverse event information database, which stores the one new characteristic or use, wherein the database comprises at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication. In fact, nothing about Applicant's method for using an identified

new use for, or characteristic of, a product of manufacture or device could be construed as an act of nature. Contrary to the Examiner's position, no agency, such as the FDA, develops a proprietary new use for, or characteristic of, a product of manufacture or device, wherein the method expressly requires creating an essential adverse event information database pertaining to patents and/or documenting inventorship, even if the subject of the new use or characteristic is a drug interaction.

The law regarding rejection under 35 USC §101 has been governed by the decision of *Diamond v. Chakrabarty*, (447 U.S. 303 (1980) *Diamond, Commissioner of Patents and Trademarks v. Charabarty, certiorari* to the US Court of Customs and Patent Appeals, No. 79-136; argued March 17, 1980; decided June 16, 1980.) The US Supreme Court ruled that a genetically engineered oil eating bacteria was patentable because it did not occur in nature and the exemption for natural process did not apply. This ruling has been expanded to allow patenting of DNA sequences and methods of testing for genetic diseases since fragments of specific cloned DNA don't occur in nature. The claims of Applicant's present invention have been narrowed to a new use of a product of manufacture or device. Hence, rejection under 35 USC §101 is not applicable.

Accordingly, Applicant's method meets the requirements of 35 USC §101, and the present rejection is moot in light of Applicant's amended claims. Applicant, therefore, respectfully asks that the rejection be withdrawn.

**Response to the Rejection under the Judicially Created Doctrine of Obviousness-Type Double Patenting**

The Examiner has maintained the rejection of Applicant's application under the judicially created doctrine of obviousness-type double patenting over Applicant's previously issued US Patent No. 6,219,674 (" the '674 patent"). In particular, the Examiner alleges that claim 201 of the present application is anticipated by claim 15 of the '674 patent, meaning that in the Examiner's opinion, "every element of claim 201" is contained in the '674 patent. However, such an assertion is incorrect because the '674 patent fails to teach each and every element of Applicant's claim 201, and therefore, fails to anticipate the presently claimed invention.

To reiterate Applicant's previous response to this rejection, the law of double patenting is concerned only with what patents claim, and "double patenting," therefore,

involves an inquiry into what, if anything, has been claimed twice. See *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 23 USPQ2d 1839, 1840 (Fed. Cir. 1992). Therefore, the only question is what is claimed in Applicant's application as compared to what was claimed in the '674 patent. When considering whether the same invention being claimed twice. The answer in the present case is "No." The element of commercializing the "new **essential** adverse event information" stored in the database is claimed in Applicant's present invention, but it is not even suggested in the claims of the '674 patent. The cited claim 15 of the '674 patent reads:

> 15. A method for creating and using product data, said method comprising the steps of:
>
> accessing at least one adverse event data source that stores adverse event data associated with a commercially available product;
>
> analyzing said adverse event data to identify new adverse events associated with the product;
>
> creating at least one adverse event information database, said creating comprising analyzing data from said at least one adverse event data source to identify at least one new use for the product responsive to identification of at least one new adverse event associated with the product, said creating further comprising storing adverse event information, said adverse event information including said at least one new use; and
>
> commercializing adverse event information stored at said at least one adverse event information database.

As can be seen upon careful review of claim 15 of the '674 patent, the accessed database includes "at least one adverse event data source" relating to a commercially available product." When that previously recorded adverse event data in the database is analyzed in claim 15, "at least one new use for the product" is identified regarding a new adverse event associated with the product. That new use information is stored as "adverse event information," and then the stored adverse event information is commercialized.

By comparison, pending claim 201 of Applicant's present invention defines a method that is quite different from claim 15 above, and requires express steps of:

documenting inventorship of the at least one new characteristic of, or use for, the product or device; and

creating a proprietary essential adverse event information database, which stores the one new characteristic or use, wherein the database comprises at least one

of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication.

In Applicant's present application, the data that is used in the method is defined as "new **essential** adverse event information" as discussed in detail in Applicant's previous response. "Essential adverse event information" is a defined term, beginning at paragraph 0085 of the specification. "The final determination of what is '**essential**' information is determined by a regulatory agency such as the FDA." See paragraph 0086. Applicant's "new adverse event information" is "essential," as further defined in paragraph 0087, specifically in terms of proprietary data.

> New adverse event information that is "essential" is of great commercial value since if this information is proprietary, for example patented in the form of a new use, it can be used to exclude potential competitors from selling a product which would require the essential information. In order for a company searching through raw adverse new uses, to maximize profits from such a search, the "essential" new uses should ideally be separated from other new uses. By limiting the protection for such new data, *e.g.*, patenting, and limiting petitions to regulatory agencies to only the "essential" new uses, a company saves time and money by avoiding expending time on adverse event information that has little commercial value.

Applicant further explains at paragraph 0094, that "[h]aving estimated the risk of an adverse event associated with a product, such as a drug, one can determine if the adverse events are essential. Several different criteria can be utilized to determine if the adverse reaction is essential," followed by a listing of non-limiting examples. By comparison, at paragraph 0095, Applicant defines an *unnecessary adverse event*, as one that "would be an essential adverse event that could be, or could have been, easily avoided. In the list that follows in paragraph 0094, a drug interaction is described as an "unnecessary adverse event," which could have been avoided by withholding one of the interacting drugs. Other such unnecessary adverse events are then listed. Paragraph 0096 describes another type of essential adverse event information, wherein risk "exceeds the benefit." Paragraph 0097 describes a third type of essential adverse event information, wherein "frequency of the adverse event is so high, or the event so severe, that [it is] a significant health concern or medical management issue" other essential adverse events in this category include marked abnormalities in laboratory values, vital

signs, EKG, and seizures. Paragraph 0098 describes a fourth type of essential adverse event information, that is so well characterized that causation is generally believed to exist, such as those detected in two separate, well-controlled clinical trials, industrial chemicals that are known to cause severe adverse events. See also paragraph 0100 describing another use of Applicant's adverse event model to develop new methods of screening drugs for adverse events.

Thus, Applicant's use of the term "new **essential** adverse event [associated with the product or device]" refers to newly created novel information. "New" does not refer to a temporal definition, such as reference to a recent event. In fact, it is a goal of Applicant's invention to search for novel adverse events that are patentable. As a result, Applicant treats recently reported adverse events (relating to the "time" the events were recorded) as "old," since adverse events reported by others are not patentable. The claims issued in the '674 patent make no reference what-so-ever to a "new essential adverse event" as defined by Applicant's present invention. Moreover, the '674 patent makes no reference to information relating to a "commercially available product" in the adverse event data source, nor to creating and forming an adverse event information database.

Therefore, returning the double patenting analysis, the answer to the initial question is: "No, the same invention is not being claimed twice." And "No," there is no claim or even suggestion, either the creation of or use of "new essential adverse event information," Applicant's present invention fails to make any requirement that a critical element of the '674 patent be present – that the stored data is associated with a "commercially available" product. As a result, even in a two way analysis the claims of the two inventions are neither the same, nor a variation of each other. Each set of claims defines different subject matter, and the two inventions are, in fact, patentably distinct, each claiming one or more unique elements that are not found in the other. Therefore, there is no double patenting, and Applicant's claims are neither anticipated by the '674 patent, nor does Applicant presently claim an obvious variation of the patented claims. Since the rejected pending claims of Applicant's invention define subject matter that is not an obvious variation of the '674 patent, Applicant's invention is necessarily patentably distinct from the '674 patent. Moreover, since Applicant's claims are not

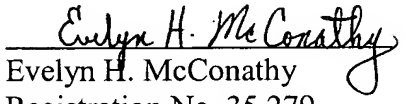
fixed until they are finally allowed, no terminal disclaimer is needed at this time. However, Applicant will re-visit this issue, if necessary, when there is an indication from the Examiner that all pending claims are allowed or allowable. Until then, Applicant asks that this rejection be withdrawn as not only improper, but also premature.

It is respectfully submitted, therefore, that Applicant's pending claims are in condition for allowance, and Applicant respectfully requests that allowance be granted at the earliest date possible. Should the Examiner have any questions or comment regarding Applicant's amendments or response, the Examiner is asked to contact Applicants undersigned representative at (215) 772-7550.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-2424. A duplicate copy of this Amendment and Response is enclosed.

Respectfully submitted,

Date: November 20, 2006



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